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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------------------------------------------------------------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/580,144 | 05/18/2006 | Jeremy Cannon | 2099.00041 | 9242 |
| 7590 | 09/12/2008 | | EXAMINER | |
| Kenneth I Kohn Kohn and Associates 30500 Northwestern Hwy Suite 410 Farmington Hills, MI 48334 | | | TANNER, JOCELIN C | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3731 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 09/12/2008 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/580,144 | CANNON ET AL. | |
| | Examiner | Art Unit | |
| | JOCELIN C. TANNER | 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 5/18/2006.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-30 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-30 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 18 May 2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Drawings

The drawings are objected to because figures 2 and 3 contain extraneous matter such as words and dimensions. Figure 1 is objected under 37 CFR 1.84(m) because of solid black shading that is not permitted and numbers and 37 CFR 1.84(p) which requires reference characters to be plain and legible. Figures 4 and 5 are objected to under 37 CFR 1.84 (i) and 37 CFR 1.84(p) because of lines, numbers and letters that are not uniformly thick and well defined, clean, durable and black and numbers and reference characters that are not plain and legible. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and

informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 14, 15, 17, 22, 23, 25 and 26 are rejected under 35

U.S.C. 102(b) as being anticipated by Yoon (US Patent No. 5,788,676).

1. Regarding claims 1-3, Yoon discloses a trocar (10) having an insert end with a housing or “chamber” (14) wherein a pair of universal seal (16a, 16b) are positioned in the proximal and distal ends of the chamber to provide an air and fluid tight seal when engaging or not engaging an instrument (column 2, lines 37-40, column 4, lines 1-10, column 7, lines 19-22, Fig.2).
2. Regarding claim 5, Yoon discloses deformable diaphragms (16a, 16b) having at least one slit (column 6, lines 60-62) through which an instrument is inserted.
3. Regarding claims 14 and 15, Yoon discloses a trocar (10) formed of plastic, metal or flexible and elastic materials, i.e. rubber (column 4, lines 18-20, 46-47).

4. Regarding claims **17**, Yoon discloses the method steps of maintaining a fluid and airtight environment including the steps of introducing a surgical instrument into patient through a trocar (10) having a fluid and airtight seal wherein a pair of universal seal (16a, 16b) are positioned in the proximal and distal ends of a chamber (14) (column 3, lines 1-16).

5. Regarding claim **22**, Yoon discloses the method step of puncturing the abdominal wall and inserting the trocar (10) through the incision (column 9, lines 4-8).

6. Regarding claim **23**, Yoon discloses the method step of creating an incision using a needle or “obturator” (column 9, lines 4-8).

7. Regarding claims **25 and 26**, Yoon discloses the method of stabilizing the trocar in the incision by engaging the endcap (54) of the chamber (Fig. 2).

8. **Claims 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by James (US Patent No. 5,279,551).**

Regarding claims **27 and 28**, James discloses the method steps including the insertion of a stylet (27) into the lumen of a trocar catheter having substance removing means wherein irrigation or suction of fluids is performed through the first lumen or “instrument lumen” (17) or the second lumen (35) via openings (25a, 25b) (column 4, lines 4-6, 55-59).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. **Claims 4, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (US Patent No. 5,788,676) in view of Vincent et al. (US Patent No. 5,658,298).**

11. Regarding claims **4, 18 and 19**, Yoon discloses an instrument inserted through resiliently engaging deformable diaphragms (16a, 16b) situated at each end of the chamber (column 3, lines 5-16) but fails to disclose an O-ring.

Vincent et al. teaches and O-ring (71) encircling the distal end of the inner shaft within the trocar cannula (column 4, lines 32-36).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided an O-ring to the trocar of Yoon, as taught by Vincent et al., as an additional safeguard for preventing deflation of the cavity during use.

12. **Claims 6 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (US Patent No. 5,788,676) in view of Riza et al. (US Patent No. 5,993,471).**

13. Regarding claim **6**, Yoon discloses deformable diaphragms that having non-aligned slits but fails to explicitly disclose perpendicular diaphragms.

Riza teaches two deformable diaphragms having slits that are perpendicular with respect to other (column 7, lines 53-56).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided consecutive diaphragms having perpendicular slits to enhance sealing structure.

14. Regarding claim **24**, Riza et al. teaches the method step of creating an incision using a stylet or “scalpel” (column 3, lines 59-61). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used a stylet to create an incision using the trocar of Yoon, as taught by Riza et al., since it was well known in the art to make an incision using a scalpel.

15. **Claims 7-10, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (US Patent No. 5,788,676) in view of James (US Patent No. 5,279,551).**

16. Regarding claims **7and 8**, Yoon discloses all of the limitations previously discussed. However, Yoon fails to disclose substance removing means and fluid flow means.

James teaches a trocar catheter having substance removing means wherein irrigation or suction of fluids is performed through the first lumen or “instrument lumen” (17) or the second lumen (35) via openings (25a, 25b) (column 55-65).

Since Yoon and James teach known elements, i.e. trocars, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the trocar of Yoon with the substance removal means and fluid flow means, as taught by James, for the predictable result of channeling fluid away from the patient.

17. Regarding claim 9, James discloses a second lumen or “downflow lumen” (35) extending through at least part of the neck portion wherein an injection port or “inlet opening” (45) introduces a fluid and inlet openings (25) for receiving treatment (column 4, lines 25-31, 33, 55-65).

18. Regarding claim 10, James teaches openings or “outlet ports” (25) from which fluid flows through and into the instrument lumen (17) (column 4, lines 55-59).

19. **Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (US Patent No. 5,788,676) in view of Kellogg (US Patent No. 5,968,060).**

20. Regarding claim 11, Yoon discloses all of the limitations previously discussed except for agitating means that are operatively connected to a trocar.

Kellogg teaches an ultrasonic trocar (10) including a handpiece assembly (50), generator (30), braking mechanism (130) and an acoustic assembly (80) through which

ultrasonic energy propagates to cause vibration within the acoustic assembly (column 3, lines 17-20, Fig. 1).

Since, Yoon and Kellogg teach known devices, i.e. trocars, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the trocar of Yoon with vibrating means, as taught by Kellogg, to minimize trauma and detect penetration.

21. Regarding claim 12, Kellogg discloses an automatic transmission component or agitator wherein the transducer assembly is adapted to vibrate at an ultrasonic frequency in response to electrical energy (column 2, lines 9-15).

22. Regarding claim 13, Kellogg teaches an automatic agitator that is an ultrasonic agitator (column 3, lines 16-20).

23. **Claim 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon (US Patent No. 5,788,676) in view of Banik et al. (US Patent No. 5,256,149)**

Regarding claim 16, Yoon discloses a trocar (10) formed of plastic or flexible and elastic materials, i.e. rubber (column 4, lines 18-20, 46-47). Yoon fails to disclose the plastic as being

Banik et al. discloses a trocar (10) constructed entirely of transparent material (column 11, lines 34-38).

Since, Yoon and Banik et al. teach known devices, i.e. trocars, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the plastic trocar of Yoon to be transparent, as taught by Banik et al., for the predictable result of exteriorly viewing the interior of a trocar during surgical techniques.

24. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over James (US Patent No. 5,279,551) in view of Yoon (US Patent No. 5,788,676).

25. Regarding claim 29, James discloses all of the limitations previously discussed except for the method step of sealing the lumen.

Yoon discloses a trocar (10) having an insert end with a housing or "chamber" (14) wherein a pair of universal seal (16a, 16b) are positioned in the proximal and distal ends of the chamber to provide an air and fluid tight seal when engaging or not engaging an instrument (column 2, lines 37-40, column 4, lines 1-10, column 7, lines 19-22, Fig.2).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the trocar of James with sealing means, as taught by Yoon, to prevent the escaping of gases through the portal during surgery.

26. Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over James (US Patent No. 5,279,551) in view of Kellogg (US Patent No. 5,968,060).

Regarding claim 30, James discloses all of the limitations previously discussed except for agitation means.

Kellogg teaches an ultrasonic trocar (10) including a handpiece assembly (50), generator (30), braking mechanism (130) and an acoustic assembly (80) through which ultrasonic energy propagates to cause vibration within the acoustic assembly (column 3, lines 17-20, Fig. 1).

Since, Yoon and Kellogg teach known devices, i.e. trocars, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the trocar of Yoon with vibrating means, as taught by Kellogg, to minimize trauma and detect penetration.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cushieri et al. (US Patent No. 5,352,206) is related to improved trocar medical devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jocelin C. Tanner/
8/15/2008
Examiner, Art Unit 3731

/Todd E Manahan/
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